REMARKS

Claims 1-34 are pending in this application. Claims 1, 2, and 4-28 are withdrawn from consideration as they are drawn to non-elected claims. Claims 3 and 29-34 are under consideration. Claim 3 has been amended. No new matter has been added by amendment. Applicants respectfully request reconsideration of the claims as amended and passage to allowance.

I. Priority

The status of the prior applications has been updated by amendment to the first paragraph of the specification.

II. Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Examiner rejects claims 3 and 29-34 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner states that the terms "less than the amount" and "reduced titer of virus infection" in claim 3 are relative terms, which renders the claim indefinite. Applicants have deleted "less than the amount" from the claim, thereby making this rejection moot. The relevant language of amended claim 3 now reads " orally administering said protective composition material such that the amount of antigenic protein administered to the animal is not sufficient to produce antibodies against said pathogen, ."

With regard to the term "reduced titer of virus infection," Applicants respectfully traverse the rejection. Applicants point out that a standard is provided for the relative term, thereby overcoming any allegation that the relative term is indefinite. The subsequent phrase "compared to an animal not administered said vaccine material" provides the standard by which the reduced

titer of virus infection may be measured. Thus, the language of claim 3, and therefore all dependent claims, contains only relative terms for which an appropriate standard is given. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

III. Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Examiner rejects claims 3 and 29-34 under 35 U.S.C. § 112, first paragraph, stating that the specification does not reasonably provide enablement for a general method of vaccinating against all antigens of all virus types. The Examiner states that undue experimentation would be required to enable the full scope of the claimed invention due to the unpredictable nature of vaccine development. Applicants respectfully traverse this rejection.

The claims are not directed to vaccine development, quite the contrary. The invention relates to the discovery that one can achieve protection WITHOUT a traditional vaccine/antibody generating protocol. The protection response observed in applicant's specification is not specific to any particular antigen and thus is applicable to a wide array of antigens since the response is not antigen specific. Further Applicant has exemplified this in the specification and as the Examiner points out in his 102 rejection, the process of generating plants which express antigens is known in the art We teach the same in our specification and Lam shows that antigens can be made and purified from transgenic plants. . We also show in our specification examples of a protective response from plant derived antigens in the absence of generation of antibodies. Application of this principle to other antigens requires no more than routine optimization of parameters as taught in the specification. Undue experimentation would not be required to

identify appropriate dosing according to the invention. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). The specification states:

> [D]osing is accomplished at much lower levels, only sufficient to generate protection, without an antibody response. Methods for dosing and regulating antibody presence are known to those of skill in the art and determination of the appropriate dose consistent with the teachings herein amounts to nothing more than routine optimization parameters. The course of immunization may be followed by assays for antibodies for the supernatant antigens. The assays may be performed by labeling with conventional labels, such as radionuclides, enzymes, fluorescers, and the like. These techniques are well known and may be found in a wide variety of patents such as U.S. Patent Nos. 3,791,932; 4,174,384 and 3,949,064, as illustrative of these types of assays.

(specification page 22, fifth paragraph).

Applicants submit that the amendment to claim 3 and the remarks presented herein alleviate the rejections under 35 U.S.C. § 112, first paragraph, and respectfully request reconsideration.

IV. Claim Rejections – 35 U.S.C. § 102

The Examiner rejects claims 3 and 30-33 under 35 U.S.C. § 102(b) as being anticipated by Lam et al (WO 94/20135). The Examiner states that the broad invention claimed by Lam et al teaches a mucosal immune response and/or humoral immune response. Applicant respectfully disagrees with the Examiner, Lam clearly presupposes an antibody response to achieve protections from its plant produced antigens. . Claim 3 as amended is drawn to a method of protecting an animal against challenge from a pathogen causing disease "wherein said protection is characterized by lack of a specific immune or antibody response." Thus, the protection claimed in the instant invention is conferred by the general immune system and is not specific to any particular pathogen.

Nowhere in Lam is there any teaching or suggestion that if you took a plant produced antigen, and presented to the animal so that no antibody response was seen, that protection from the disease could be seen.

The Examiner cites from Lam the statement on page 8 that mucosal "and/or" humoral immune responses are possible. But, a complete reading of that sentence, and of the Lam application, shows Lam was insistent that an antibody response had to be obtained. In Lam mucosal immunity is defined as follows:

> Animal and human subjects infected by a pathogen present an immune response when overcoming the invading microorganism. They do so by initiating at least one of three branches of the immune system: mucosal, humoral or cellular. *Mucosal immunity results from the production of secretory IgA antibodies* in the secretions that bathe mucosal surface in the respiratory tract, the gastrointestinal tract, the genitourinary tract and the secretory glands...Mucosal antibodies act to prevent colonization of the pathogen on mucosal surfaces thus establishing a first line of defense against invasion. The production of mucosal antibodies can be initiated by either local immunization of the secretory gland or tissue or by presentation of the antigen to either the gut-associated lymphoid tissues (GALT; Peyer's Patches) or the bronchial-associated lymphoid tissue (BALT)....Humoral immunity, on the other hand, results from the production of IgG and IgM antibodies in the serum....

When Lam refers to mucosal immunity it requires that IgG antibodies be made. When in Lam it refers to priming "the mucosal immune system and/or stimulate the humoral immune response" it was concerned with the issue that while doses need to be high enough to generate the response they wanted (an antibody response) they should not be so high as to induce systemic tolerance. It did not vary from their requirement and teaching that an antibody needs to be produced. The entire sentence reads, "In a more highly preferred embodiment, the mucosal immunogens of the invention are those mucosal immunogens which prime the mucosal immune system and/or stimulate the humoral immune response in a dose-dependent manner, without inducing systemic tolerance and without the need for excessive doses of antigen." Later in the specification it is

stated that "Whichever mode of introduction of the vaccine to the mammalian subject is selected, it will be understood by those skilled in the art of vaccination that the selected mode must achieve vaccination at the lowest dose possible in a dose-dependent manner *and by doing so elicit serum and/or secretory antibodies* against the immunogen of the vaccine with minimal induction of systemic tolerance."

Applicant's invention is distinct from Lam in that it requires NO antibody response.

Lam et al do not teach the concept that administering a oral vaccine material expressed in a plant can provide general, non-specific protection against pathogens including protection against antigens other than those used to elicit the response. As this is an essential feature of the claimed invention, Applicants submit that Lam et al fails to anticipate independent claim 3 and therefore dependent claims 30-33. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

VI. Conclusion

Applicants submit that in light of the foregoing amendments and remarks, claims presented herein are in condition for allowance.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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